

GHTF

GLOBAL HARMONISATION

BY

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MEDICAL DEVICE REGULATIONS IN EUROPE

- Until the 1980's there were many different levels of regulation within the European Community.

MEDICAL DEVICES REGULATION IN EUROPE

There are now 3 main Medical Devices Directives:

- 90/385/EEC
 - - Active Implantable Medical Device Directive
- 93/42/EEC
 - - European Directive on Medical Devices
- 98/79/EC
 - - In-vitro diagnostic Medical Devices Directive

GLOBAL REGULATIONS

No Consistency between Europe, USA, Canada, Japan, Australia and many other parts of the world have little or no established regulations

Result – Initiative in 1991 to Investigate Global Procedures



G M D N – HISTORY

1991

FIRST ATTEMPTS AT GLOBALISATION

**TALKS BETWEEN FDA & EUROPEAN
COMMISSION**



1991 – AUTUMN
CONFERENCE IN BRUSSELS

TO EXPLORE EXISTING M.D.NOMENCLATURES

RESULT – NO CONCLUSION



TALKS ON GLOBAL HARMONISATION

- Exploratory Meeting in Nice during Global Manufacturers Meeting to discuss ‘Good Manufacturing Practices’
- Present: FDA, European Commission, Health-Canada, TGA-Australia, MHW-Japan.



HISTORY OF GHTF

- 1990-Talks Between FDA & European Commission at Director Level
- 1991-Conference on Common Medical Device Nomenclature
- 1992-Meeting at NICE Global Med.Dev.Congress Present - FDA + E.Commission + Japan-MHW + Industry
- 1st Agreement to Study Processes of Good Manufacturing Practices

AIM- TO ACHIEVE COMMON APPROACH



REGULATED G.M.P'S IN 1992

EUROPE - Based on ISO 9000 Standards

FDA - G.M.P - Under Review

JAPAN - Good Importer Practice - Still developing

CANADA - Considering Regulations (probably like FDA)

AUSTRALIA - Considering Regulations

3/1/2002



GLOBAL HARMONISATION

- First Formal Meeting of GHTF in Tokyo 1993
- Try to establish a consistent approach to GMP-by using as a basis ISO 9001 as the reference for regulations introducing the use of Quality Systems



HISTORY GHTF CONTD

1993 - MEETING IN TOKYO-1ST FORMAL MEETING

GHTF ESTABLISHED 3 REGIONS

**EUROPE - EUROPEAN COMMISSION
EFTA STATES
EUROPEAN INDUSTRY (EUCOMED,
COCIR, IAPM, EUROM 6)**

**USA +
CANADA - FDA, HIMA, NIMA, HEALTH CANADA**

**JAPAN +
AUSTRALIA - MHW, JFMDA, TGA**

15/09/00



1993-1995

Agreed approach based on ISO 9000 Standards
plus additional medical device supplements

EUROPE - Directives included this approach

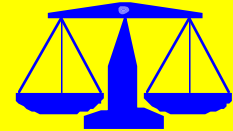
**FDA - Changed G.M.P to include similar ISO 9000
+ features**

**CANADA- Developed regulation using evolving GHTF
work (including ISO 9000+)**

**JAPAN- Abandoned G.I.P. and wrote new ISO 9000 +
system**

AUSTRALIA- Started to mirror the European Approach

4/3/2002



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GLOBAL HARMONISATION

- Study Groups established to explore: -
 - SG1- Pre-market Technical Documentation
 - SG2- Reporting procedures following incidents
 - SG3- Quality Systems and Design Validation
 - SG4- Common Procedures to audit manufacturers Quality System

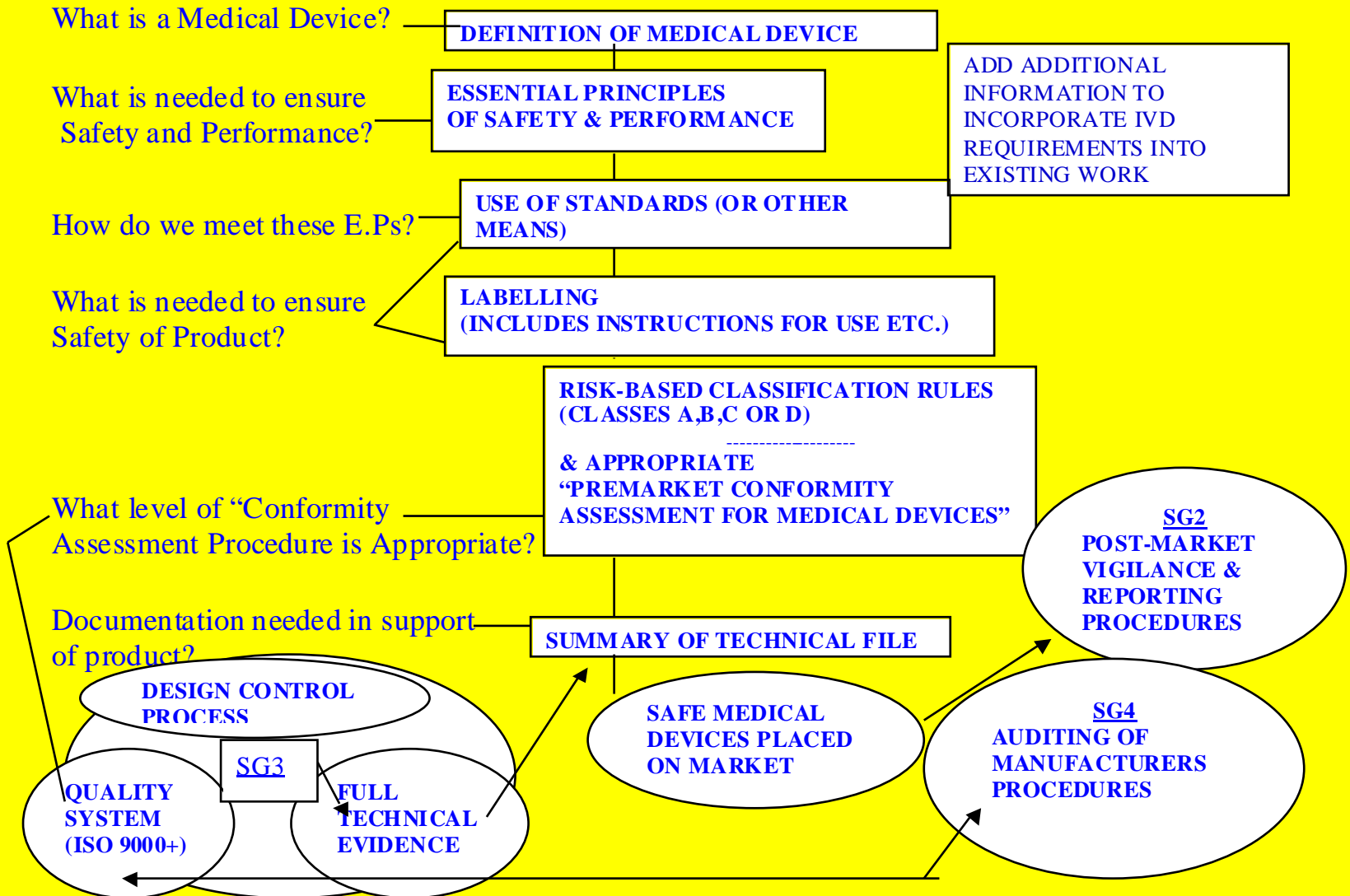


**Meetings of GHTEF every 12 to 18
months with Study Group Meetings as
needed**

Secretariat held originally by Europe
– now rotates between 3 regions



SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS



DOCUMENTS ACCEPTED BY GHTF AS GHTF - FINAL DOCUMENTS

GHTF-SG1-N020R5 - Essential Principles of Safety & Performance
of Medical Devices

GHTF-SG1-N0120 - “The Role of Standards in the Assessment of
Medical Devices”

GHTF-SG1-N009R6 - “Labelling Recommendations for Medical
Devices”



SG1 - WORKING DOCUMENTS

“RECOMMENDATIONS ON MEDICAL DEVICES CLASSIFICATION”

Based upon 4 RISK CLASSES - A-B-C-D

This Document - previously issued as a Proposed Document - has been further developed to include more detail to indicate the guiding principles used for establishing which Risk Class is appropriate for a given device.



SG1 WORKING DOCUMENTS

“PREMARKET REGULATORY CONFORMITY ASSESSMENT (INCLUDING NEEDS FOR CLINICAL EVALUATION) - THE LINKS WITH DEVICE CLASS

This is a revised heading of an original subject - “Guidance on Clinical Evaluation” and is now linked to device class and relevant conformity assessment



NEW WORK (Part 1)

HARMONIZED CONFORMITY ASSESSMENT REQUIREMENTS - LINKED TO RISK CLASS

**Consolidated answers to a number of questions related to each of
Device Classes**

- **Need for a Quality System?**
- **Scope for a Quality System?**
- **Use of Standards?**
- **Use of comparison with aspects of other devices already on market?**
- **Use of Clinical Evidence?**
- **Sources of Clinical Evidence?**
- **Need for Clinical Investigation?**
- **Manufacturer maintains complete Technical Documentation?**



NEW WORK (Part 2)

CONFORMITY ASSESSMENT - CONTINUED

- **Use of Standards?**
- **Scope of Pre-market Technical Information available to support a new device placed on market (STED)?**
- **Need to submit STED?**
- **Need for audit of manufacturers quality system (certification)?**
- **Need for product-related pre-market audit?**
- **Need for Declaration of Conformity with Essential Principles?**
- **Need for Registration/Listing of Device with each Authority?**
- **Need to demonstrate existence of Post-market surveillance system?**



SG1 - WORKING DRAFT

**SG1-NO11-R14- “Summary Technical File for
Premarket Documentation of Conformity with
Requirements for Medical Devices”**

**PILOT STUDIES BEING APPLIED TO ASSIST
IN DEVELOPMENT OF THIS DOCUMENT**



OTHER SG1 - WORK

Information document concerning the definition of the term “medical device”

Investigation of NEEDS for In Vitro Diagnostic Medical Devices in relations to existing SG1 documents.

Examination and comment on existing and new regulations from other parts of the world.



Harmonized definition of the term “medical device”

‘Medical device’ means an instrument, apparatus/implement/machine, appliance, implant, material or other similar or related article, whether used alone or in combination, including accessories and the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of :

- Diagnosis, prevention, monitoring, treatment or alleviation/mitigation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for injury,
- Investigation, replacement, modification, or support of the anatomy/body structure or of a physiological process,
- Supporting and sustaining life,
- Control of conception,
- Disinfection of medical devices,
- in vitro examination of specimens derived from the human body.
 - and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.



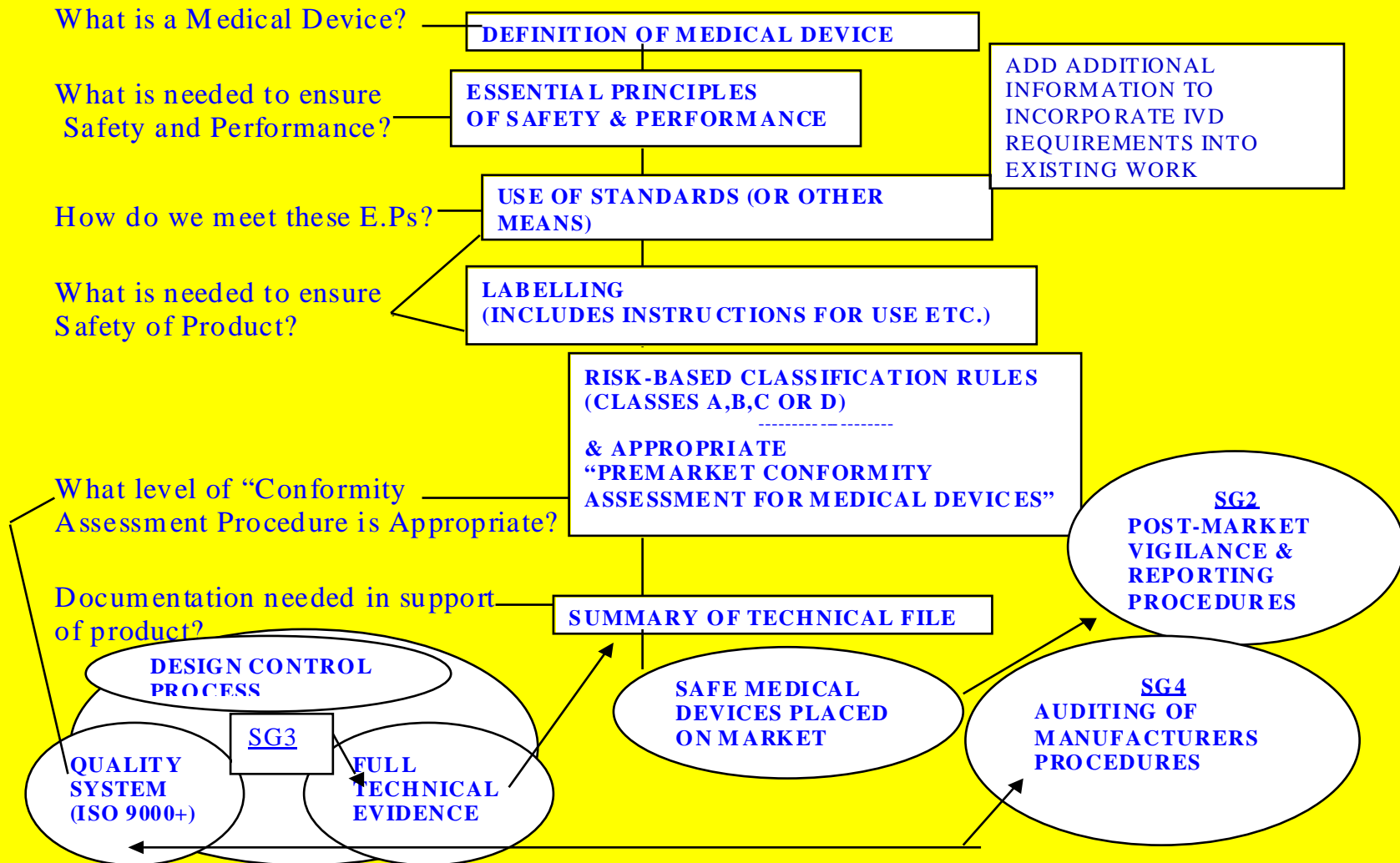
Scope

Products, which are considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- Aids for disabled/handicapped people,
- Devices for the treatment/diagnosis of diseases and injuries in animals,
- Spare parts for medical devices,
- Devices incorporating animal and human tissues which may meet the requirements of the above definition but be subject to different controls.



SCOPE OF GHTE-SG1 PREMARKET TECHNICAL REQUIREMENTS



What is a Medical Device?

DEFINITION OF MEDICAL DEVICE

What is needed to ensure Safety and Performance?

ESSENTIAL PRINCIPLES OF SAFETY & PERFORMANCE

ADD ADDITIONAL INFORMATION TO INCORPORATE IVD REQUIREMENTS INTO EXISTING WORK

How do we meet these E.Ps?

USE OF STANDARDS (OR OTHER MEANS)

What is needed to ensure Safety of Product?

LABELLING (INCLUDES INSTRUCTIONS FOR USE ETC.)

RISK-BASED CLASSIFICATION RULES (CLASSES A,B,C OR D) & APPROPRIATE "PREMARKET CONFORMITY ASSESSMENT FOR MEDICAL DEVICES"

What level of "Conformity Assessment Procedure is Appropriate?"

SUMMARY OF TECHNICAL FILE

SG2 POST-MARKET VIGILANCE & REPORTING PROCEDURES

Documentation needed in support of product?

DESIGN CONTROL PROCESS
QUALITY SYSTEM (ISO 9000+)
SG3
FULL TECHNICAL EVIDENCE

SAFE MEDICAL DEVICES PLACED ON MARKET

SG4 AUDITING OF MANUFACTURERS PROCEDURES

GLOBAL HARMONISATION

- Study Groups established to explore: -
 - SG1- Pre-market Technical Documentation
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LINKS WITH STANDARD ACTIVITIES

SG1 Document on “Use of Standards” to address
“Essential Principles” document

SG1 Document - Summary Technical File -
indicates the link with standards to illustrate needs

SG1-SG3 Documents refer to Conformity
Assessment procedures following Standards

SG4 Auditing Documents development of ISO
standard plus regulatory needs

SG2 Reporting System will utilise International
Standard Nomenclatures



Use of Standards to support subjects covered by GHTF Essential Principles (1)

- Essential Principle

- Assessment of Risks & Benefits
- Safety principles - design & construction
- Reliability/Consistency of performance during lifetime
- Transport & Storage - effect on performance
- Undesirable side effects to be identified & quantified

- Standard

- Standard - Risk Management
- Many Standards - family or specific
- Many Standards - family or specific
- Specific Standards
- Many Specific Standards



GENERAL STATEMENTS ON GHTF DOCUMENTS (1)

- This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement.
- It is intended for use by medical device Regulators, Conformity Assessment Bodies and Industry - and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices, in the interest of Public Health



GENERAL STATEMENTS ON GHTE DOCUMENTS (2)

- The document will be of value to countries developing or amending regulations.
- The regulatory requirements of some countries may not, at present, reflect the contents of this document.



1992 – 1993

COMMISSION MANDATE TO CEN TO
DEVELOP STRUCTURE FOR FUTURE
NOMENCLATURE



CEN PROJECT TEAM ESTABLISHED
TO DEVELOP

CEN/ISO NOMENCLATURE

BASED ON STANDARD



WHY DO WE NEED A NOMENCLATURE?

**ANSWER: -
FOR DATA EXCHANGE PURPOSES**

**ECRI SYSTEM PROPOSED AS INTERIM
MEASURE**

AGREEMENT BETWEEN CEN & ECRI



GLOBAL HARMONISATION

- Europe had identified the need for work to establish a Nomenclature for Medical Devices so that each group of Devices could have a consistent Generic description.
- The Global Harmonisation work emphasised the need for a Nomenclature on a Global basis.



EUDAMED

European Database on Medical Developments



Nomenclature System (1)

12 main categories of devices

- Active implantable devices
- Anaesthetic & respiratory devices
- Dental devices
- Electro/medical & electro/mechanical medical devices
- Hospital hardware
- In vitro diagnostic devices



NOMENCLATURE SYSTEM (2)

- Non active implantable devices
- Ophthalmic and optical devices
- Re-useable surgical instruments
- Single use devices
- Technical aids for disabled persons
- Diagnostic & therapeutic radiation devices



ADOPTION OF NOMENCLATURE

This is the most comprehensive Medical Device Nomenclature available-- requests for use of Nomenclature are being received from Regulators in many parts of the world and thus it will be established as the Global Nomenclature for use by Regulators, Manufacturers, and for Commercial Identification purposes.

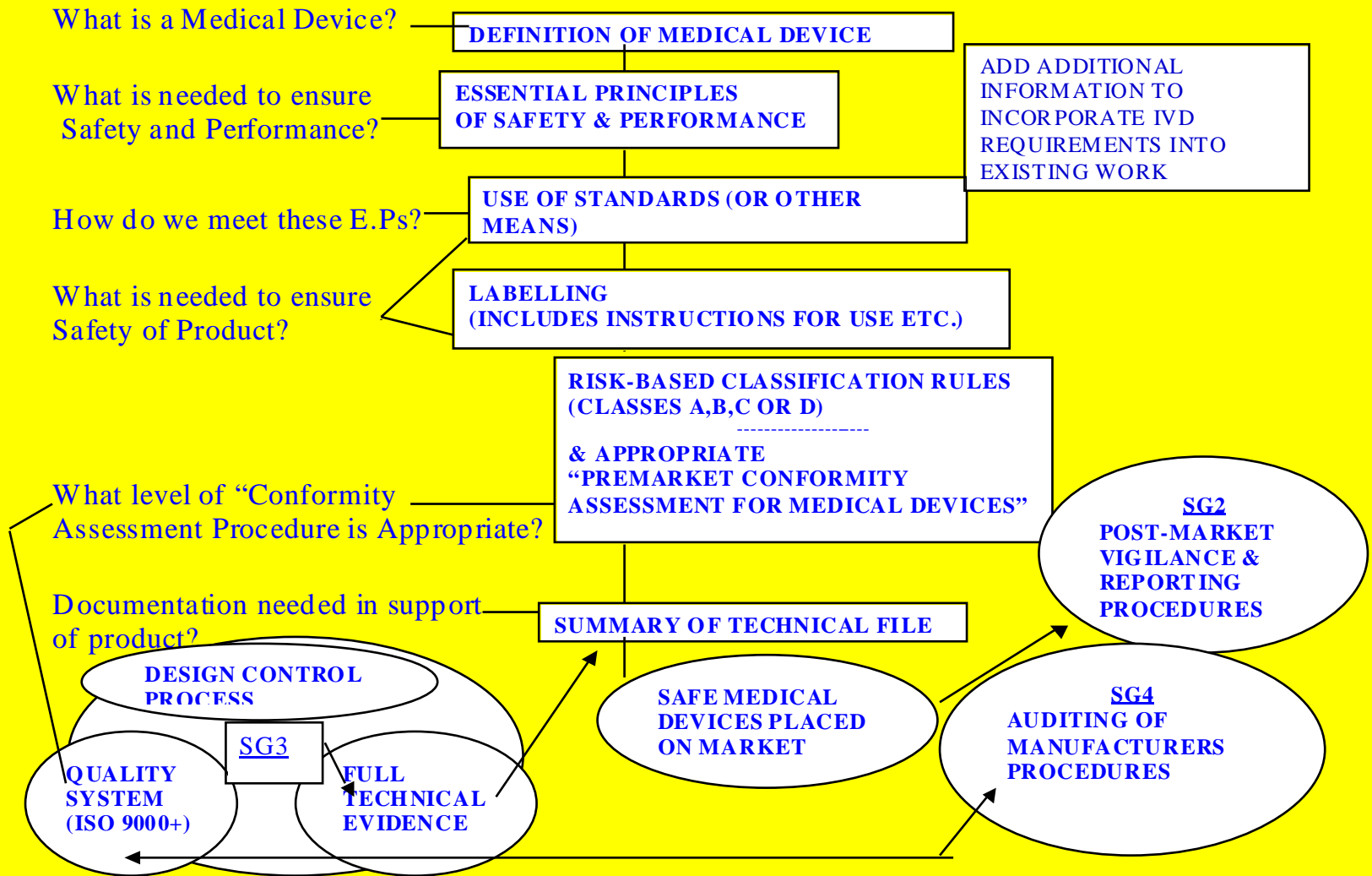


MAINTENANCE AGENCY

- Present temporary secretariat for the Maintenance Agency BSI
- Nomenclature available as searchable CD or by electronic means
- Cross Reference available to other Nomenclatures used in the development of GMDN



SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS



The Development of the GMDN owes much to those who gave so much time and also thanks should be conveyed to those providing information through existing Nomenclatures: -

ECRI – UMDNS

NKKN

JFMDA

EDMA

FDA

